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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,387	03/26/2003	Maurizio Dalle Carbonare	2039-0156P	6340
2292 7590 05/31/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER MAEWALL, SNIGDHA	
			ART UNIT 1615	PAPER NUMBER
			NOTIFICATION DATE 05/31/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/019,387	Applicant(s) DALLE CARBONARE ET AL.	
	Examiner Snigdha Maewall	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. Receipt of applicants Arguments/Remarks, Amendments and IDS filed on 08/07/2006 and 08/09/2006 is acknowledged.

Claims 3-17 are pending in this application, claims 3-17 will be prosecuted on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 3-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 3 recites the limitation as a method of treatment of scarring on the skin which comprises applying across a wound in the surface of the skin a pharmaceutical composition or biomaterial comprised of at least one hyaluronic acid derivative acid derivative selected from the group consisting of an

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ester with an alcohol, an auto-crosslinked ester, a crosslinked derivative, a hemiester of succinic acid with hyaluronic acid, an O-sulphated derivative and an O/N sulphated derivative, optionally in association with at least one additional pharmacologically or biologically-active compound. Recourse to the specification does not define the expression "applying across a wound in the surface of the skin". As such, the expression "applying across a wound in the surface of the skin constitutes the new matter". Accordingly, this is a new matter rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 provides for the use of hyaluronic acid derivative for the treatment of scarring on the skin but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 4 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). is acknowledged.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/04828 ('828) in view of WO 94/17837 ('837).

'828 disclose compositions comprising hyaluronic acid derivatives and methods of using said hyaluronic acid-based compositions to treat the formation of post-surgical adhesion and scar formation (abstract and page 51). Like the instant application, '828 discloses that the following set of hyaluronic acid derivatives can be used to treat adhesion and scar formation: (1) hyaluronic acid derivatives esterified with alcohols; (2) autocrosslinked esters of hyaluronic acid; (3) crosslinked hyaluronic acid compounds;

(4) hemiesters of succinic acid; (5) N sulphated derivatives of hyaluronic acid; and (6) amide derivatives of hyaluronic acid (See page 4, lines 1-28). The above hyaluronic acid derivatives can be formulated as gels and additional pharmacologically active substances, such as antibiotics, may also be used the method (Claims 1-33).

'828 does not specifically teach skin scar treatment.

However, ('837) teaches a multilayer nonwoven material, comprising a surface layer which comes into contact with the skin, and one or more other layers which do not come into contact with the skin, wherein said surface layer which comes into contact with the skin is at least one derivative of hyaluronic acid. The derivative of hyaluronic acid is hyaluronic acid ester (abstract). Example 1-7 on page 7 depicts the use of hyaluronic acid benzyl ester. ('837) further discloses that the multilayer nonwoven materials are used in dermatology such as treating the skin pathologies (page 3, lines 22-24 and claim 30).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to use hyaluronic acid ester for the treatment of scarring on the skin by using the composition provided by ('828). A skilled artisan would have been motivated to use derivatives of hyaluronic acid such as esters of hyaluronic acid in treating the scarring of the skin with a reasonable expectation of success.

8. Claims 3-10 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/07833 ('833) in view of WO 94/17837 ('837).

'833 discloses hyaluronic acid derivatives capable of being used for post-surgical adhesion (abstract). As set forth in '833, an "adhesion" is a permanent scar that connects two adjacent surfaces (page 2, lines 1-10). Like the instant application, '828 discloses that the following set of hyaluronic acid derivatives can be used to treat adhesion and scar formation: (1) hyaluronic acid derivatives esterified with alcohols; (2) autocrosslinked esters of hyaluronic acid; and (3) crosslinked hyaluronic acid compounds (page 9, lines 1-12; page 12, Example 3; page 14, lines 1-35; page 30, lines 29-35 and page 31, lines 1-25;). The above hyaluronic acid derivatives can be formulated as gels and additional pharmacologically active substances, such as heparin, may also be used the method (Claims 1, 10 and page 31, Table 1).

('833) does not specifically teach skin scar treatment.

However, ('837) teaches a multilayer nonwoven material, comprising a surface layer which comes into contact with the skin, and one or more other layers which do not come into contact with the skin, wherein said surface layer which comes into contact with the skin is at least one derivative of hyaluronic acid. The derivative of hyaluronic acid is hyaluronic acid ester (abstract).). Example 1-7 on page 7 depicts the use of hyaluronic acid benzyl ester (page 3, lines 22-24 and claim 30).

('837) further discloses that the multilayer nonwoven materials are used in dermatology such as treating the skin pathologies.

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to use hyaluronic acid ester for the treatment of scarring on the skin

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by using the composition provided by ('833) as (837) teaches the treatment of skin pathologies. A skilled artisan would have been motivated to use derivatives of hyaluronic acid such as esters of hyaluronic acid in treating the scarring of the skin with a reasonable expectation of success.

Response to Arguments

9. Applicant's arguments are considered but are moot in view of the new ground(s) of rejection.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

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Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600